Amendments to the Drawings:

Please replace drawing sheets 1/38, 2/38, 3/38, 4/38, 5/38, 7/38, 8/38, 10/38, 11/38, 12/38, 16/38, 18/38, 21/38, 22/38, 26/38, 28/38, 29/38, 34/38, and 38/38 with Replacement Sheets 1/38, 2/38, 3/38, 4/38, 5/38, 7/38, 8/38, 10/38, 11/38, 12/38, 16/38, 18/38, 21/38, 22/38, 26/38, 28/38, 29/38, 34/38, and 38/38.

Replacement Sheets 1/38, 2/38, 3/38, 4/38, 5/38, 7/38, 8/38, 10/38, 11/38, 12/38, 16/38, 18/38, 21/38, 22/38, 26/38, 28/38, 29/38, 34/38, and 38/38 are attached hereto.

The attached drawing sheet 1/38 replaces the original sheet 1/38. In Replacement Sheet 1/38, "Figure 1" is relabeled as "Figure 1A", and the "A" is deleted from the upper left corner of the figure.

The attached drawing sheet 2/38 replaces the original sheet 2/38. In Replacement Sheet 2/38, "Figure 1a" is deleted, "Figure 1B" is added above the top figure, the "B" is deleted from the upper left corner of the top figure, "Figure 1C" is added above the bottom figure, and the "C" is deleted from the upper left corner of the bottom figure.

The attached drawing sheet 3/38 replaces the original sheet 3/38. In Replacement Sheet 3/38, "Figure 2" is relabeled as "Figure 2A", the "A" is deleted from the upper left corner of the top figure, and sequence identifiers (e.g., SEQ ID NO:11) are added in Figure 2A.

The attached drawing sheet 4/38 replaces the original sheet 4/38. In Replacement Sheet 4/38, "Figure 2a" is relabeled as "Figure 2B", and the "B" is deleted from the upper left corner of the figure.

The attached drawing sheet 5/38 replaces the original sheet 5/38. In Replacement Sheet 5/38, "Figure 2b" is deleted, "Figure 2C" is added above the top figure, the "C" is deleted from the upper left corner of the top figure, "Figure 2D" is added above the bottom figure, and the "D" is deleted from the upper left corner of the bottom figure.

The attached drawing sheet 7/38 replaces the original sheet 7/38. In Replacement Sheet 7/38, "Figure 4" is deleted, "Figure 4A" is added above the top figure, the "A" is deleted from the upper left corner of the top figure, "Figure 4B" is added above the bottom figure, and the "B" is deleted from the upper left corner of the bottom figure.

The attached drawing sheet 8/38 replaces the original sheet 8/38. In Replacement Sheet 8/38, "Figure 4a" is relabeled as "Figure 4C", and the "C" is deleted from the upper left corner of the figure.

The attached drawing sheet 10/38 replaces the original sheet 10/38. In Replacement Sheet 10/38, "Figure 5a" is relabeled as "Figure 5 (continued)".

The attached drawing sheet 11/38 replaces the original sheet 11/38. In Replacement Sheet 11/38, "Figure 6" is deleted, "Figure 6A" is added above the top figure, the "A" is deleted from the upper left corner of the top figure, "Figure 6B" is added above the bottom figure, the "B" is deleted from the upper left corner of the bottom figure, and a sequence identifier (i.e., SEQ ID NO:51) is added to Figure 6B.

The attached drawing sheet 12/38 includes changes to Figure 6C. This sheet replaces the original sheet 12/38. In Replacement Sheet 12/38, "Figure 6a" is relabeled as "Figure

6C", and the "C" is deleted from the upper left corner of the figure.

The attached drawing sheet 16/38 replaces the original sheet 16/38. In Replacement Sheet 16/38, sequence identifiers (e.g., SEQ ID NO:9) are added to Figure 10.

The attached drawing sheet 18/38 replaces the original sheet 18/38. In Replacement Sheet 18/38, sequence identifiers (e.g., SEQ ID NO:58) are added to Figure 12.

The attached drawing sheet 21/38 replaces the original sheet 21/38. In Replacement Sheet 21/38, "Figure 15" is replaced with "Figure 15A", and the "A)" is deleted from the upper left corner of the figure.

The attached drawing sheet 22/38 replaces the original sheet 22/38. In Replacement Sheet 22/38, "Figure 15a" is replaced with "Figure 15B", and the "B)" is deleted from the upper left corner of the figure.

The attached drawing sheet 26/38 replaces the original sheet 26/38. In Replacement Sheet 26/38, sequence identifiers (e.g., SEQ ID NO:63) are added to Figure 19.

The attached drawing sheet 28/38 replaces the original sheet 28/38. In Replacement Sheet 28/38, "Figure 21" is replaced with "Figure 21A", and sequence identifiers (e.g., SEQ ID NO:73) are added.

The attached drawing sheet 29/38 replaces the original sheet 29/38. In Replacement Sheet 29/38, "Figure 21A" is replaced with "Figure 21B".

The attached drawing sheet 34/38 replaces the original sheet 34/38. In Replacement Sheet 34/38, "Figure 26" is deleted, "Figure 26A" is added above the top figure, the "A" is deleted from the upper left corner of the top figure,

"Figure 26B" is added above the bottom left figure, the "B" is deleted from the upper left corner of the bottom left figure, "Figure 26C" is added above the bottom right figure, the "C" is deleted from the upper left corner of the bottom right figure, and sequence identifiers (e.g., SEQ ID NO:83) are added to Figure 26A.

The attached drawing sheet 38/38 replaces the original sheet 38/38. In Replacement Sheet 38/38, "Figure 30" is deleted, "Figure 30A" is added above the top left figure, the "A" is deleted from the upper left corner of the top left figure, "Figure 30B" is added above the top right figure, the "B" is deleted from the upper left corner of the top right figure, "Figure 30C" is added above the bottom figure, the "C" is deleted from the upper left corner of the bottom figure, and sequence identifiers (e.g., SEQ ID NO:89) are added to Figure 30C.

REMARKS

Claims 1-12, 14, 16, 19-29, and 31-35 are pending in the subject application. Of these, claims 1-2, 7-12, 14, 21-29, and 31-35 have been withdrawn pursuant to a restriction requirement. Hereinabove, no claims have been canceled; no claims have been amended; and no new claims have been added. Therefore, claims 3-6, 16, and 19-20 are now pending and under consideration. In view of the foregoing amendments and the following remarks, applicants respectfully request reconsideration of the restriction requirement, objections, and rejections set forth in the outstanding office action.

The first part of the action relates to the previously imposed requirement for restriction. In response to the March 13, 2008, Written Restriction Requirement, applicants elected Group II (claims 3-5 and 16). The PTO then telephonically modified the restriction requirement. In response to the telephonically-modified restriction requirement, applicants telephonically elected modified Group I (claims 1-5, 16, and 19-20) and sub-Group A (limiting the method claims to in vitro methods). Applicants hereby affirn this election.

The outstanding office action correctly sets forth the modified Restriction Requirement in writing and correctly reports our telephonic response. However, in the last paragraph on page 7 of the outstanding office action, the PTO incorrectly sets forth the claims that are withdrawn and those that are under consideration. In particular, the PTO states that claims 1-2, 7-12, 14, 21-29, and 31-35 are withdrawn, and

that claims 3-6, 16, and 19-20 are under consideration. Claim 6 should have been withdrawn as it belongs to non-elected modified Group II (directed to cells); claims 1-2 should not have been withdrawn because they belong to elected modified Group I. Correctly stated, claims 6-12, 14, 21-29, and 31-35 should be withdrawn, and claims 1-5, 16, and 19-20 should be under consideration.

Applicants respectfully request that the next office action correctly state the claims that are withdrawn and those that are under consideration.

Since the office action's substance is based an erroneous statement of which claims are withdrawn and which are under consideration, applicants have responded to the substance of the rejections and objections as thoroughly as possible. However, applicants reserve the right to modify their response once the PTO corrects its statement of which claims are under consideration and addresses the patentability of those claims.

The second part of the office action acknowledges the present applications claim of priority and indicates that UK 0316725.1 disclosed the elected invention. Since there is some confusion in the outstanding office action as to which claims are part of the "elected invention", applicants request that this acknowledgment be repeated once the PTO corrects its statement of which claims constitute the elected invention.

The third part of the office action sets forth some problems with the Information Disclosure Statement ("IDS"). In particular, the two foreign documents cited on the first page of the IDS need to be re-submitted. Also, the Examiner has objected to the way in which the Genbank references were

cited in the IDS. Applicants are making the necessary changes on the PTO-1449 and will file a Supplemental IDS under separate cover.

The fourth part of the outstanding office action objects to Figures 2, 10, 12, 19, 21, 25, 26, and 30 because they do not include sequence identifiers. Also, the numbering of Figure 4A and Figure 6A is objected to because, it is said, the application contains two Figures 4A and two Figures 6A.

With regard to the absence of sequence identifiers, applicants have hereinabove added sequence identifiers to Figures 2 (drawing sheet 3/38), 10 (drawing sheet 16/38), 12 (drawing sheet 18/38), 19 (drawing sheet 26/38), 21 (drawing sheet 28/38), 26 (drawing sheet 34/38), and 30 (drawing sheet 38/38). Applicants have also added a sequence identifier to Figure 6B (drawing sheet 11/38). With regard to Figure 25, it is not clear which sequence information requires sequence identifiers. In this regard, it is noted that the amino acid labels on the x-axes of the bar graphs represent single amino acids, one for each bar in the bar graph.

With regard to there being two Figures 4A and Figures 4B, applicants have amended the drawing sheets corresponding to Figure 4 (drawing sheets 7/38 and 8/38) and Figure 6 (drawing sheets 11/38 and 12/38). Similarly, applicants have amended the drawing sheets corresponding to Figure 1 (drawing sheets 1/38 and 2/38), Figure 2 (drawing sheets 3/38, 4/38, and 5/38), Figure 5 (drawing sheets 9/38 and 10/38), Figure 15 (drawing sheets 21/38 and 22/38), Figure 21 (drawing sheets 28/38 and 29/38), Figure 26 (drawing sheet 34/38), and Figure 30 (drawing sheet 38/38).

A detailed explanation of the changes made in Replacement Sheets 1/38, 2/38, 3/38, 4/38, 5/38, 7/38, 8/38, 10/38, 11/28, 12/38, 16/38, 18/38, 21/38, 22/38, 26/38, 28/38, 29/38, 34/38, and 38/38 is set forth on pages 33-36 hereinabove.

In view of the above, applicants respectfully submit that the objections to the drawings, as set forth in the fourth part of the outstanding office action, should be reconsidered and withdrawn.

The fourth part of the outstanding office action also objects to the specification for containing hyperlinks. In this regard, the outstanding office action refers to MPEP § 608.01. MPEP § 608.01 states:

> Examiners must review patent applications to make certain that hyperlinks and other forms of browser-executable code, especially commercial site URLs, are not included in a patent application. . . . Examples of a hyperlink or a browser-executable code are a URL placed between these symbols "< >" and http:// followed by a URL address. When a patent application with embedded hyperlinks and/or other forms of browser-executable code issues as a patent (or is published as a patent application publication) and the patent document is placed on the USPTO web page, when the patent document is retrieved and viewed via a web browser, the URL is interpreted as a valid HTML code and it becomes a live web link. When a user clicks on the link with a mouse, the user will be transferred to another web page identified by the URL, if it exists, which could be a commercial web site. USPTO policy does not permit the USPTO to link to any commercial sites since the USPTO exercises no control over the organization, views or accuracy of the information contained on these outside sites.

Applicants have hereinabove amended the specification by replacing browser executable text (i.e., http:// followed by a URL address) with the corresponding bare URL address (i.e., without the "http://" prefix). As amended, the specification does not contain hyperlinks or other forms of browser-executable code, and accordingly, applicants respectfully submit that the objections to the specification, as set forth in the fourth part of the outstanding office action, should be reconsidered and withdrawn.

The fifth part of the outstanding office action objects to the specification for disclosing sequences that are not identified by a sequence identifier number. In response, applicants have amended the specification to add the required sequence identifier numbers. In view of the above, applicants respectfully submit that the objections to the specification, as set forth in the fifth part of the outstanding office action, should be reconsidered and withdrawn.

The sixth part of the outstanding office action objects to the claims for not beginning with a sentence of which the claims are an object. In response, applicants have hereinabove amended the application by replacing "CLAIMS:" with "WE CLAIM:" on page 163, line 1. In view of the above, applicants respectfully submit that the objections to the claims, as set forth in the sixth part of the outstanding office action, should be reconsidered and withdrawn.

The seventh part of the outstanding office action rejects claims 3-5, 16, 29[1], and 20 under 35 U.S.C. § 112,

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[1] Applicants believe that the PTO may have meant to reject claim 19 instead of claim 29 under 35 U.S.C. § 112, second

second paragraph, as being indefinite. Applicants respectfully traverse this rejection.

The outstanding office action states that claim 3 is indefinite because it is not clear whether the claim refers to a composition comprising only purified LKB1, purified STRAD, and purified recombinant MO25 or to some other composition, such as a cellular lysate. The outstanding office goes on to assert that the skilled artisan would not know the metes and bounds of the recited invention because the meaning of the term "purified" is not provided in the claims nor in the specification. Applicants disagree. Applicants submit the one skilled in the art would have understood the metes and bounds of the recited invention in view of the specification's teaching, such as the teaching set forth at page 23, lines 24-27, where it is stated:

> By "purifed" is meant that the preparation has been at least partially separated from other components in the presence of which it has been formed, for example other components of a recombinant cell. Examples of methods of purification than may be used are described in the Examples.

For at least this reason, applicants respectfully submit that the rejection of claim 3 under 35 U.S.C. § 112, second paragraph, for indefiniteness should be reconsidered and withdrawn.

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paragraph. In this regard it is noted that: claim 29 has been withdrawn from consideration; claim 29 does not depend from claim 3; and claim 19 depends from claim 3.

Claims 4-5, 16, and 20 are said to be indefinite for the same reason as claim 3 because they are dependent on claim 3. For at least the reasons set forth above, the rejection of claim 3 for indefiniteness should be reconsidered and withdrawn. For at least these same reasons, applicants respectfully submit that the rejection of claims 4-5, 16, and 20 under 35 U.S.C. § 112, second paragraph, for indefiniteness should be reconsidered and withdrawn.

The outstanding office action also states that claim 19 is indefinite because it recites "identifying a compound for modulating cellular LKB1 activity . . .a preparation according to claim 3". Claim 3 is said to refer to a non-cellular composition, and, therefore, the PTO concludes that it is unclear whether claim 19 refers to a cellular method or an in vitro method. In the end, the PTO states that, for the purposes of examination, it is assumed that claim 19 is meant to recite "identifying a compound for modulating LKB1 activity in vitro . . .a preparation according to claim 3".

Applicants disagree with the alleged lack of clarity and to the outstanding office action's rewording of claim 19. With regard to the lack of clarity, the use of the word "cellular" is in the preamble. Thus, the method of claim 19 is for identifying a compound that modulates cellular LKB1 activity (i.e., a compound that modulates LKB1 activity in a cell). The remainder of the claim sets out the method by which such a compound is to be identified. The method for identifying such a compound is carried out with a purified (e.g., a non-cellular) preparation of claim 3. The facts (i) that the method for identifying a compound may be carried out in vitro and (ii) that the compound, once identified, may be

capable of modulating cellular (i.e., in vivo) LKB1 activity does not render the claim indefinite. For at least this reason, applicants respectfully submit that the rejection of claim 19 under 35 U.S.C. § 112, second paragraph, for indefiniteness should be reconsidered and withdrawn.

Claim 20 is said to be indefinite for the same reason as claim 19 because claim 20 is dependent on claim 19. For at least the reasons set forth above, the rejection of claim 19 for indefiniteness should be reconsidered and withdrawn. For at least these same reasons, applicants respectfully submit that the rejection of claim 20 under 35 U.S.C. § 112, second paragraph, for indefiniteness should be reconsidered and withdrawn.

The outstanding office action also states that claims 19 and 20 are indefinite because the contain improper antecedent usage. More particularly, it is said that, in claim 29, the phrase "a preparation according to claim 3" should be corrected to "the preparation according to claim 3". No reason is provided. Applicants note that claim 3 is not directed to a single preparation but encompasses many preparations. Therefore, the PTO's requirement that "a" be replaced with "the" is improper. For at least these reasons, applicants respectfully submit that the rejection of claims 19-20 under 35 U.S.C. § 112, second paragraph, for improper antecedent usage should be reconsidered and withdrawn.

For all of the above reasons, applicants request that the rejection of claims 3-5, 16, 29[1], and 20 under 35 U.S.C. § 112, second paragraph, as being indefinite be reconsidered and withdrawn.

The eighth part of the outstanding office action rejects claims 3-5, 16, 29[2], and 20 under 35 U.S.C. § 112, first paragraph, as being indefinite. Applicants respectfully traverse this rejection.

The outstanding office action states that claims 3-6, 16, 19, and 20 are so broad as to encompass any composition comprising any LKB1 protein, any STRAD protein, and any recombinant MO25 protein. The outstanding office action asserts that the scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of compositions comprising an extremely large number of proteins broadly encompassed by the claim. The PTO goes on to point out that, since the amino acid sequence of a protein determines its structural and functional properties, predictability of which changes can be tolerated in a proteins amino acid sequence and obtain the desired LKB1, STRAD, MO25 activities requires a knowledge of and guidance with regard to which amino acids in the protein's sequence, if any, are tolerant of modification and which are conserved (i.e., expectedly intolerant to modification), and detailed ways in which the protein's structure relates to its function. The PTO then asserts that, in this case, disclosure is limited to the LKB1 protein disclosed in Boudeau et al., "Heat-Shock Protein 90 and Cdc37 Interact with LKB1 and Regulate its Stability," Biochem. J., 370:849-857 (2003) ("Boudeau"). In

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[2] Applicants believe that the PTO may have meant to reject claim 19 instead of claim 29 under 35 U.S.C. § 112, first paragraph. In this regard it is noted that claim 29 has been withdrawn from consideration and that portions of this rejection refer to claim 19.

subsequent paragraphs, the PTO further asserts that the specification fails to support the broad scope of claims 3-6, 16, and 19-20 because the specification does not establish: (A) the structural identity of any STRAD or MO25 protein; (B) regions of the protein structure which may be modified without affecting the desired LKB1, STRAD, and MO25 activities; (C) the general tolerance of LKB1, STRAD, and MO25 activities to modification of the proteins and extent of such tolerance; (D) a rational and predictable scheme for modifying any residues with an expectation of obtaining the desired biological function; and (E) which of the essentially infinite possible choices of proteins is likely to have desired LKB1, STRAD, and MO25 activities.

Applicants disagree.

With regard to LKB1, as the specification discusses at page 12, line 22 to page 14, line 2,

> [t]he term LKB1 will . . . be well known to those skilled in the art. The LKB1 used in the assay may be recombinant or non-recombinant. The LKB1 may be bacterially expressed, but it is preferred that it is expressed in a mammalian system and/or expressed alongside STRAD and/or MO25, preferably both, for example as described in Examples 1 and 2. The LKB1 may have the amino acid sequence of a naturally occuring LKB1, or may be a fusion polypeptide (for example as described in the Examples), or may be a fragment or variant of a naturally occuring LKB1 that retains the ability to phosphorylate or activate AMPK, for example on Thr172 of AMPK, for example as described in Example 2. Thus, the LKB1 is an LKB1 that retains an active kinase domain. A fragment of LKB1 which contains the intact kinase domain but not other regions of LKB1 may be useful; this region of

LKB1 is sufficient to retain protein kinase activity and to interact with STRAD. The LKB1 used in the assay is not a kinase-dead mutant such as is described in the Examples. It is preferred that the LKB1 retains the ability to interact with STRAD and/or MO25, as discussed further below.

Accession numbers for LKB1 include the following:

AAC15742 Peutz-Jeghers syndrome protein [Homo sapiens]
gi|3063585|gb|AAC15742.1|[3063585]

Q15831 Serine/threonine protein kinase 11 (Serine/threonine-protein kinase LKB1)
gi|3024670|sp|Q15831|STKB_HUMAN[3024670]

NP_000446 serine/threonine protein kinase 11 [Homo sapiens]
gi|4507271|ref|NP_000446.1|[4507271]

It is particularly preferred, although not essential, that the LKB1 polypeptide has at least 30% of the enzyme activity of full-length human LKB1 with respect to the phosphorylation of full-length human AMPKa1 on residue Thr172 (preferably in the presence of STRAD and MO25) or a peptide substrate encompassing this region, or phosphorylation of myelin basic protein. It is more preferred if the LKB1 polypeptide has at least 50%, preferably at least 70% and more preferably at least 90% of the enzyme activity of full-length human LKB1 with respect to the phosphorylation of full-length human AMPKa1 on residue Thr172 (preferably in the presence of STRAD and MO25) or a peptide substrate encompassing this region.

Applicants submit that, in view of the above-quoted passage, the PTO is incorrect in its assertion that, in this case,

disclosure is limited to the LKB1 protein disclosed in Boudeau. Moreover, as noted in the above passage, a fragment of LKB1 which contains the intact kinase domain but not other regions of LKB1 is sufficient to retain protein kinase activity and to interact with STRAD. Thus, the outstanding office action is also incorrect in its assertion that the specification does not establish regions of the protein structure which may be modified without affecting the desired LKB1 activity.

While it is recognized that not every possible modification to LKB1 sequence has been identified and enabled, such is not the requirement of the 112 enablement requirement. What is necessary is that the specification's teaching be commensurate with the scope of the claims. Applicants have identified several suitable LKB1s which can be used in the practice of the claimed invention, and applicants submit that other LKB1s are known to those skilled in the art and that one skilled in the art would readily be able to identify other LKB1s suitable for use in the practice of the claimed invention. Applicants have identified the domain that is sufficient for retaining LKB1 activity. Applicants have identified the levels of activity (relative to that of full-length human LKB1) suitable for use in the practice of the claimed invention.

In view of the above, it is submitted that the specification's teaching is indeed commensurate with the scope of the claims with regard to LKB1.

With regard to STRAD, as the specification discusses at page 14, line 4 to page 15, line 8,

Similarly, the terms STRAD or MO25 will similarly be well known to those skilled in the art. For example, a STRAD polypeptide (STRADα) is described in Baas et al (2003) EMBO J 22(12), 3062-3072 and in EMBL/GenBank Accession No AF308302. Human STRADα and STRADβ (NCBI accession number AAM19143) sequences are shown in Figure 10. MO25 polypeptides are described in Miyamoto et al (1993); Karos & Fisher (1999) and Nozaki et al (1996) and, for example, in Accession No NP_057373 (human MO25α) and Q9H9S4 (human MO25β). Further examples of MO25 polypeptides are shown in Figure 2 and further Accession Nos are given in the figure legend. MO25 bears no sequence homology to other proteins in the database but recent studies indicate that it is structurally related to the Armadillo repeat domain (Milburn et al., 2003). The STRAD or MO25 used in the assay may be recombinant or non-recombinant. The STRAD or MO25 may be bacterially expressed, but it is preferred that they are expressed in a mammalian system and/or expressed alongside LKB1, for example as described in Examples 1 and 2. The STRAD or MO25 may have the amino acid sequence of a naturally occuring STRAD or MO25, or may be a fusion polypeptide (for example as described in the Examples), or may be a fragment or variant of a naturally occuring STRAD or MO25 that retains the ability for the STRAD to bind to the MO25 and to LKB1, and for the MO25 to bind to the STRAD or complex of LKB1 and STRAD. At least the C-terminal region of MO25 may be required. In view of the sequence conservation throughout the length of MO25 it is considered that it may be desirable to use full length MO25. It is preferred that the STRAD polypeptide has the C-terminal sequence Trp-Asp/Glu-Phe (which MO25 is considered to recognise) but this is not considered to be essential, because MO25 can bind to STRAD lacking these residues when the STRAD is bound to LKB1 (see Example 1). It is also preferred that the pseudokinase domain of STRAD is present, as this may be required for MO25

> binding. For example, it is preferred that the STRAD is not a fragment lacking the residues corresponding to the C-terminal 88 amino acids of full length STRADα (which has a truncated pseudokinase domain and does not interact with human LKB1 or MO25α). It may be desirable to use full length STRAD.

Applicants submit that, in view of the above-quoted passage, the PTO is incorrect in its assertion that the specification fails to establish the identity of any STRAD or MO25 protein. Moreover, as noted in the above passage, the specification does indeed identify those portions of the STRAD and MO25 proteins that are believed to be important to their ability to interact with other components of the preparation. Thus, the outstanding office action is also incorrect in its assertion that the specification does not establish regions of the protein structure which may be modified without affecting the desired STRAD or MO25 activity.

While it is recognized that not every possible modification to the STRAD and MO25 sequences has been identified and enabled, such is not the requirement of the 112 enablement requirement. Again, what is necessary is that the specification's teaching be commensurate with the scope of the claims. Applicants have identified several suitable STRADs and MO25s which can be used in the practice of the claimed invention, and applicants submit that other STRADs and MO25s are known to those skilled in the art and that one skilled in the art would readily be able to identify other STRADs and MO25s suitable for use in the practice of the claimed invention. Applicants have also identified those portions of

the STRAD and MO25 proteins that are believed to be important to STRAD and MO25 activity.

In view of the above, it is submitted that the specification's teaching is indeed commensurate with the scope of the claims with regard to STRAD and MO25.

For all of the above reasons, applicants request that the rejection of claims 3-5, 16, 29[2], and 20 under 35 U.S.C. § 112, first paragraph, as lacking enablement be reconsidered and withdrawn.

The ninth and last part of the outstanding office action rejects claims 3-5, 16, 19, and 20 under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Applicants respectfully traverse this rejection.

The outstanding office action bases this rejection on an assertion that the specification fails to disclose the exact structural identity of any STRAD or MO25 protein.

Applicants disagree.

For example with regard to STRAD, at page 14, lines 5-9, the present specification states that "a STRAD polypeptide (STRADα) is described in Baas et al (2003) EMBO J 22(12), 3062-3072 and in EMBL/GenBank Accession No AF308302. Human STRADα and STRADβ (NCBI accession number AAM19143) sequences are shown in Figure 10."

With regard to MO25, at page 14, lines 9-13, the present specification states: "MO25 polypeptides are described in Miyamoto et al (1993); Karos & Fisher (1999) and Nozaki et

al (1996) and, for example, in Accession No NP_057373 (human MO25α) and Q9H9S4 (human MO25β). Further examples of MO25 polypeptides are shown in Figure 2 and further Accession Nos are given in the figure legend."

Moreover, the specification teaches DNA constructs that can be used to express STRAD and MO25. For example, DNA constructs used to express MO25α are described at page 82, lines 6-16; DNA constructs used to express MO25β are described at page 82, line 16 to page 83, line 2; DNA constructs used to express STRADα are described at page 83, lines 2-8; and DNA constructs used to express STRADβ are described at page 83, lines 10-18.

For all of the above reasons, applicants submit that there is ample written description of the claimed invention and request that the rejection of claims 3-5, 16, 19, and 20 under 35 U.S.C. § 112, first paragraph, as lacking written description be reconsidered and withdrawn.

As mentioned above, the outstanding office action has erroneously withdrawn Group I claims 1-2 from consideration, and these claims were not examined in the outstanding office action. Nothing contained in this response should be construed as pertaining to claims 1 and 2. Applicants will respond to any rejections and/or objections with regard to claims 1 and 2 only if and when such rejections and/or objections are made.

In view of the foregoing, it is submitted that this case is in condition for allowance, and such allowance is earnestly solicited.

Dated: November 19, 2008

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Peter Rogalskyj